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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,938	09/30/2003	Peter David Rathjen	DAV1189.001AUS	2369

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EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/675,938

**Applicant(s)**

RATHJEN ET AL.

**Examiner**

Allison M Ford

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of producing mesodermal cells, classified in class 435, subclass 377.
- II. Claim 16, drawn to mesodermal cells, classified in class 435, subclass 1.1.
- III. Claims 17-24, drawn to a method for monitoring differentiation/proliferation of mesodermal cells, classified in class 435, subclass 7.21.
- IV. Claims 25- 34, drawn to a method for tissue repair, regeneration and/or augmentation, classified in class 623, subclass 23.72.
- V. Claim 35, drawn to a composition comprising a modulator and a carrier, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and IV are independent. The inventions are independent and distinct, each from the other because the groups are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions. Inventions I, III, and IV are directed to methods that recite structurally and functionally distinct steps, are not required one for the other, and achieve different goals. In the instant case Invention I requires generation of embryoid bodies (EBMs) in MEDII, which is not required by any of the other methods. Invention III requires contacting cells with a ligand for the surface marker

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*brancyury*, which is not required for the other methods. Invention IV requires introducing mesodermal cells into a subject, which is not required by any of the other methods.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention II, the mesodermal cells can be obtained by removing mesodermal tissue from an animal, such as in the case of organ harvesting.

Inventions I and V are independent. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Invention V is directed to a composition comprising a modulator of mesodermal cell generation and a pharmaceutically acceptable carrier. Invention I is a method that specifically requires the modulator bone morphogenetic protein 4, but does not disclose any requirement of a pharmaceutical carrier. Therefore the inventions are distinct and independent.

Inventions II, III and V are also independent. Inventions are independent if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Invention II is not used by the method of Invention III. Invention II is directed to fully differentiated mesodermal cells; while Invention III is a method for monitoring the changes in a differentiating cell. Inventions II and V are disclosed as capable of use together.

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Invention II is directed to mesodermal cells; while Invention V is directed to the composition of a modulator and a pharmaceutically acceptable carrier. There is no method disclosed that combines the two products. Inventions III and V have different functions and different effects. Invention III is a method to screen for a change in a developmental stage of a differentiating mesodermal cell. Invention V is a composition for the purpose of delivering a modulator to cells in a pharmaceutically acceptable carrier.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II can be used for materially different purposes, other than for the method of Invention IV. The mesodermal tissue of Invention II can be used as a source of food for other animals, such as carnivores.

Inventions IV and V are independent. Inventions are independent if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, they have different functions and different effects. The method of Invention IV is used to repair, regenerate and/or augment tissues. The product of Invention V is a composition, which is not used in tissue repair or augmentation. The product of Invention V is used to deliver materials to modulate generation of mesodermal cells; the method of Invention IV makes use of fully differentiated mesodermal tissues.

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Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Haynes on 8/9/04 a request was made for a written restriction to be mailed out. An election of Inventions and affirmation of this election must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-4.

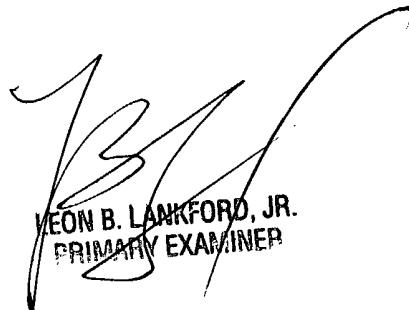
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford  
Examiner  
Art Unit 1651

AMF



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER